

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

*DMB*

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**Psychopharmacologic Drugs Advisory Committee; Notice of Meeting**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Psychopharmacologic Drugs Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on February 14 and 15, 2001, 8 a.m. to 5 p.m.

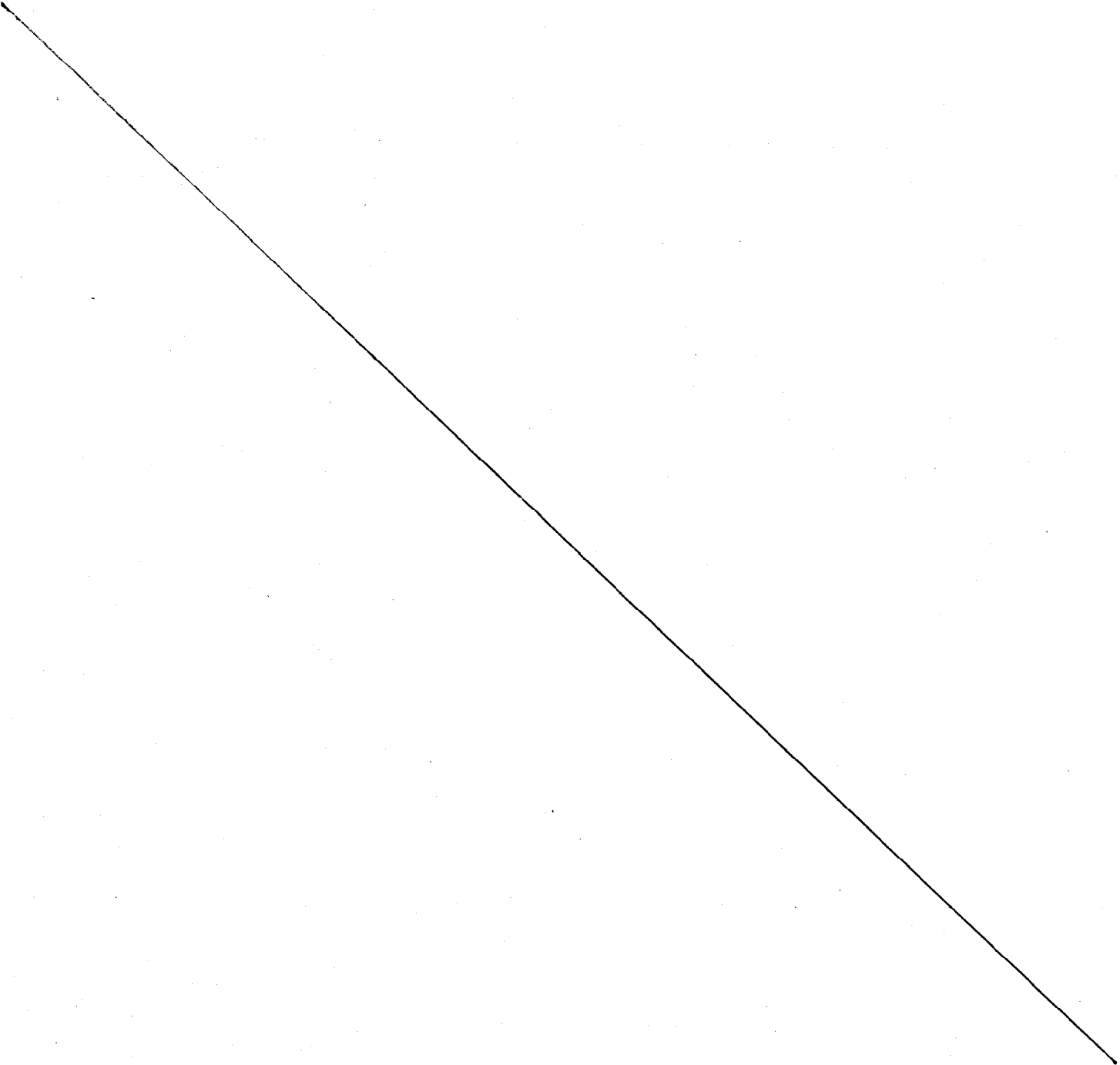
*Location:* Holiday Inn, The Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

*Contact Person:* Sandra I. Titus or Lauren W. Parcover, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, e-mail: Tituss@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area) code 12544. Please call the Information Line for up-to-date information on this meeting.

*Agenda:* On February 14, 2001, the committee will consider the safety and efficacy of new drug application (NDA) 21-253, Zyprexa® (olanzapine intramuscular, Eli Lilly, Inc.), proposed for the rapid control of agitation. On February 15, 2001, the committee will consider the safety and efficacy of NDA 20-919, Zeldox™ (ziprasidone mesylate intramuscular, Pfizer, Inc.), proposed for the acute control and short-term management of the agitated psychotic patient.

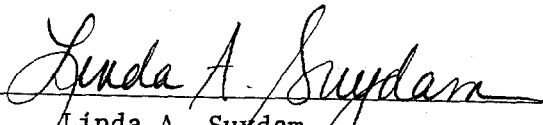
*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person

by February 7, 2001. Oral presentations from the public will be scheduled each day between approximately 1 p.m. to 1:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 2, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.



Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: December 28, 2000.

  
Linda A. Suydam,  
Senior Associate Commissioner.

CERTIFIED TO BE A TRUE  
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[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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